

K961157

510(k) Statement

Device:

Classification Name:	Screw, Fixation, Bone
Classification No.:	Class II, 87HWC, 888.3040
Common/Usual Name:	Cancellous Bone Screw
Proprietary Name:	Whiteside Biomechanics Cancellous Bone Screw

Manufacturer Identification:

Whiteside Biomechanics
12634 Olive Blvd.
Creve Coeur, MO 63141

Establishment Registration Number: 1932213

Device Description:

The Whiteside Biomechanics Cancellous Bone Screw is a self-tapping screw. The head of the screw has a standard (3.5mm) hexagonal socket drive and the underside is radiused (0.172") to fit a ballnose countersunk hole (0.344"). The thread is generally a helical spiral about the screw's longitudinal axis and has a large outer diameter (6.5mm) designed to affix in healthy cancellous bone.

The insertion of the Whiteside Biomechanics Cancellous Bone Screw is similar to most registered bone screws on the market today. After determining the need for additional fixation the surgeon drills a pilot hole, using a depth gauge to determine the proper screw length, and drives the screw into the prepared hole using a socket-driver with a hexagonal head.

Intended Use:

This bone fixation screw is intended for human implantation into prepared bone during orthopedic surgery when the surgeon determines the need for additional fixation (example: fixation of acetabular cup in total hip replacement, fracture fixation, tibial tray fixation, etc.). There is a broad spectrum of uses for this device and the specific use should be determined by the surgeon using sound medical judgment.

Additional Information:

This cancellous bone screw is made of wrought titanium 6Al-4V (ASTM F136) and is available in 5mm increments from 15mm to 50mm. These bone screws will be provided sterile and double pouched. Resterilization of screws upon contamination is not recommended. DO NOT RESTERILIZE.

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